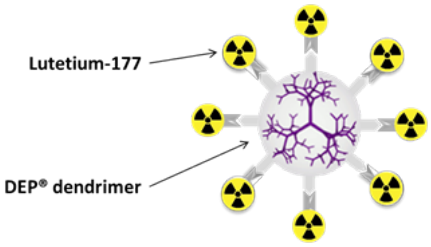
ASX Announcement

# DEP® lutetium effective in human prostate cancer model

- **As part of its expansion of DEP® applications, Starpharma has developed a number of novel radiotherapeutic and radiodiagnostic candidates**
- **Starpharma's first DEP® radiotherapy candidate (DEP® lutetium) showed highly statistically significant anticancer activity, tumour regression and 100% survival in a human prostate cancer model (DU-145)**
- **Radiotherapy is an increasingly important area in cancer therapy both clinically and commercially, and has recently been the subject of multiple high value transactions[1]**

**Melbourne, Australia; 17 June 2020:** Starpharma (ASX: SPL, OTCQX: SPHRY) today announced results from its first radiotherapeutic candidate, DEP® lutetium. DEP® lutetium is a patented nanoparticle which incorporates the radioisotope Lutetium-177 on a DEP® dendrimer scaffold.




Graphical representation of DEP® lutetium

In these studies, conducted at the University of Queensland's Centre for Advanced Imaging, the efficacy of two dose regimens of DEP® lutetium were assessed in a human prostate cancer model (DU-145). DEP® lutetium showed statistically significant and durable anticancer activity and was extremely well tolerated in both dose regimens.

Both doses of DEP® lutetium (1 x 15 MBq or 2 x 9 MBq) achieved significant anticancer activity ($p<0.0001$) in the DU-145 prostate cancer model. In addition a single dose (Day 1) of DEP® lutetium (15 MBq) achieved significant anti-tumour activity with tumour regression of over 55% (Day 36) and 100% survival (>70 days).

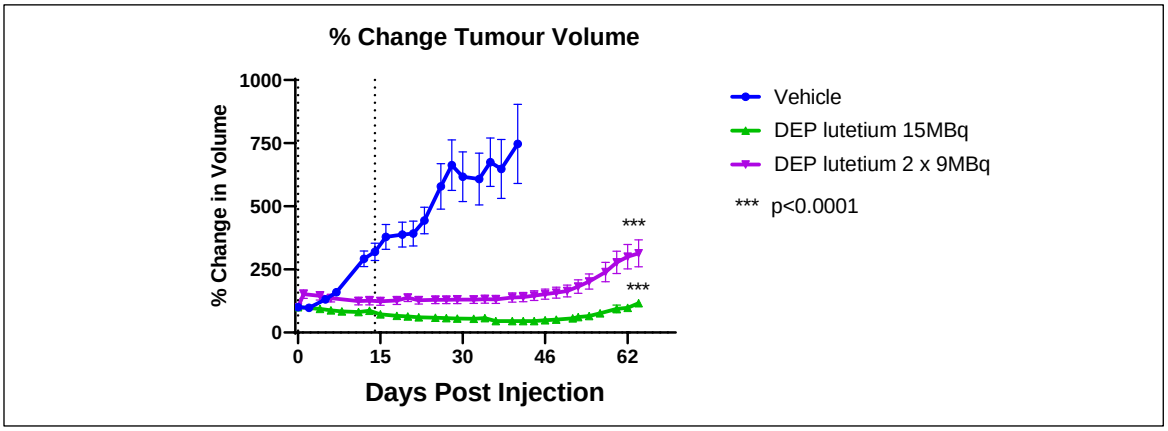



Figure 1: Percentage change in tumour volume over time as measured in the DU-145 human prostate cancer model.

[1] Acquisition of Endocyte by Novartis for US$2.1 billion and the acquisition of Sirtex by CDH Genetech for ~A$1.9 billion

Both dose regimens of DEP® lutetium were extremely well tolerated and showed minimal weight loss during dosing with recovery and subsequent weight gain.

The impressive efficacy seen with both doses of DEP® lutetium resulted in a statistically significant positive survival benefit (p<0.0001 ANOVA – Log rank (Mantell Cox) test; Figure 2).

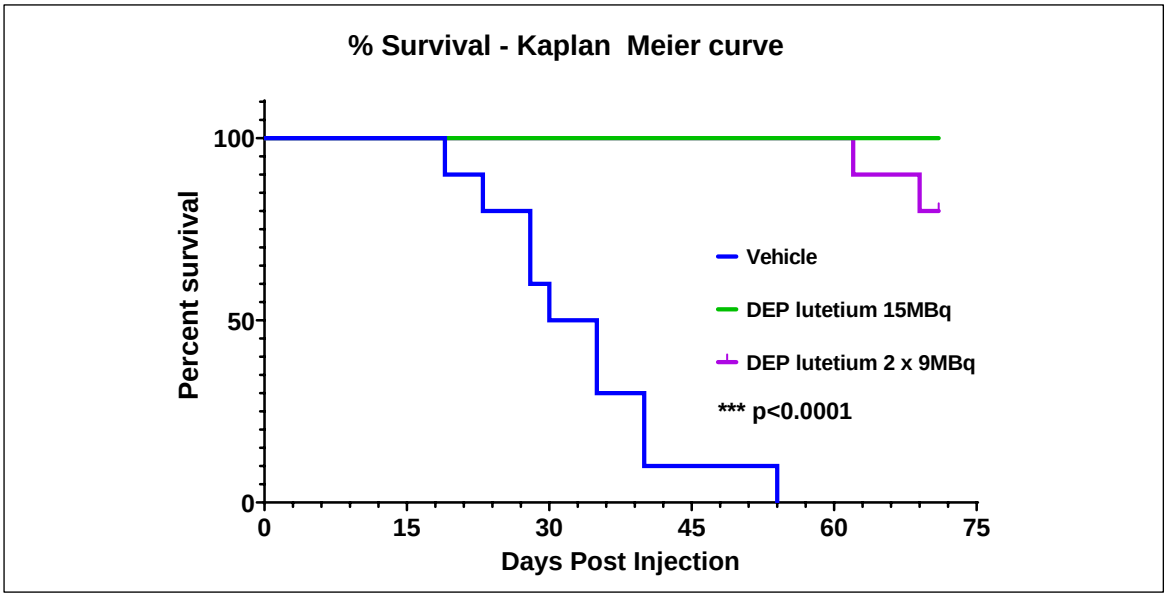



Figure 2: Kaplan-Meier survival curve in the DU-145 human prostate cancer model.

Dr Jackie Fairley, Starpharma CEO, commented: "Radiotherapeutics are a rapidly growing and increasingly important area of cancer therapy, and represent an exciting extension of the DEP® platform. The impressive efficacy and survival benefit of DEP® lutetium illustrates the versatility of Starpharma's DEP® platform. DEP® lutetium is one of several promising DEP® radiotherapeutic candidates in development. We are delighted to be working with Professor Kristofer Thurecht at the University of Queensland's Centre for Advanced Imaging, whose team are at the forefront of this innovative area."

The radiopharmaceuticals area is a rapidly developing area of cancer treatment and diagnosis, and this area has recently generated several high-value deals and sales in this category are estimated to grow to $12–15 billion by 2030[2].

## Study Methods

This study was a mouse xenograft using DU-145 human prostate cancer cells and was conducted by the University of Queensland's Centre for Advanced Imaging. Balb/c mice were injected subcutaneously with DU-145 cells into the right flank of each mouse (10 mice/group).

Groups were dosed as follows:

- Vehicle - IV vehicle on days 1, 8 and 15
- DEP® lutetium 15 MBq – IV on day 1
- DEP® lutetium 2 x 9 MBq - IV on days 1 and 15

[2] Nuclear medicine world market report & directory, MEDraysintell, 2016

Tumours were measured 2-3 times weekly using electronic callipers. Tumour volume ($mm^3$) was calculated at each timepoint. The tumour volume data represent the mean ± standard error of the mean (SEM). Note: If error bars do not display on the graphs, they are not visible because they are shorter than the height of the symbol.

## About DEP® radiopharmaceuticals

The versatility of the DEP® platform means it can be used with a wide range of therapies (e.g. small molecules, peptides, antibodies, antibody fragments, radioisotopes). DEP® radiotherapeutics incorporate radioisotopes on to the DEP® scaffold. Whilst this announcement relates to a radiotherapeutic (DEP® lutetium), the DEP® platform is applicable to both radiotherapeutic and radiodiagnostic applications. DEP® radiopharmaceutical conjugates have the potential to minimise off target toxicity and enhance efficacy when used alone or in combination with other therapeutic approaches. Specific patent applications for DEP® lutetium and further DEP® radiotherapeutic candidates have been filed.

### About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX:SPHRY), located in Melbourne Australia, is an ASX 300 company and is a world leader in the development of dendrimer products for pharmaceutical, life science and other applications.

Starpharma's underlying technology is built around dendrimers – a type of synthetic nanoscale polymer that is highly regular in size and structure and well suited to pharmaceutical and medical uses. Starpharma has two core development programs: VivaGel® portfolio and DEP® drug delivery with the Company developing several products internally and others via commercial partnerships.

VivaGel®: Starpharma's women's health product - VivaGel® BV is based on SPL7013, astodrimer sodium, a proprietary dendrimer. VivaGel® BV for bacterial vaginosis (BV), is available for sale under the brand names Betafem® BV Gel (UK), Betadine BV™ (Europe), Betadine™ BV Gel (Asia) and Fleurstat BVgel (Australia and New Zealand) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel® BV to ITF Pharma for the US; Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel® condom (an antiviral condom which includes VivaGel® in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel® condom has been launched in Japan under Okamoto's 003 brand, and in Australia and Canada under the LifeStyles Dual Protect® brand. The VivaGel® condom is approved in Europe.

DEP® - Dendrimer Enhanced Product®: Starpharma's DEP® drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP® programs, including improved efficacy, safety and survival. Starpharma has three internal DEP® products – DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan - in clinical development in patients with solid tumours. Starpharma's partnered DEP® programs include a multiproduct DEP® licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more. In June 2019 Starpharma signed a Development and Option agreement with AstraZeneca for a DEP® version of one of AstraZeneca's major marketed oncology medicines.

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Disclosure
This ASX Announcement was authorised for release by the Chairman, Mr Rob Thomas.

### Forward Looking Statements

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.